AN INTEGRATED SOFTWARE SYSTEM FOR MEDICAL EQUIPMENT MANAGEMENT

Z. Bliznakov, N. Pallikarakis
Department of Medical Physics, School of Medicine, University of Patras, 26500, Rio - Patras, Greece

Abstract-**The evolution of biomedical technology has led to enhanced use of medical devices in healthcare delivery. Clinical Engineering Departments (CEDs), in order to improve their services and monitor the outcomes, are introducing more and more telematic means. In the present work, a new computerized, integrated, windows oriented system intended for CED management is proposed. The system model is based on a star architecture, whose implementation has been carried out by a set of software units, addressing predefined CED specific tasks. Practical usefulness of the whole system has been demonstrated on a pilot evaluation trial. Its adoption could improve and speed up the management processes and maintenance services provided by the CED in the hospitals.**

I. Introduction

Medical devices are used today in virtually every health care delivery process. Whether equipment is used for diagnosis, monitoring of patient condition, or therapy, the health care facility should ensure that the equipment is performing as intended by the manufacturer.

In order to satisfy the increased needs for medical equipment management, Clinical Engineering Departments (CEDs) are turning towards computerization as the only viable solution. This imposes the use of software tools, specifically designed for medical equipment management. These tools offer many benefits compared to the manual paper work, facilitating data processing and analysis. Furthermore, it is efficient and easy to work with such systems, since they offer many attractive features. For example, the CED administration disposes, at any time, full complex and extremely precise “picture” of the working status of medical devices, thus assuring efficient device operation and high patient safety [1,2].

This paper presents a global information system, integrating a number of software packages, serving specific management processes, each of them able to work either as a stand alone application, or interlinked between each other through properly designed communication tools and facilities.

II. Methodology

The appropriate and efficient use of this integrated system is inevitably related to the proper functionality differentiation of each specific module and their synchronized work. System development followed the well-established phases of *Requirement analysis*, *Design*, *Implementation* and *Evaluation*.

A. Requirement analysis

The main objective of such an integrated software system is to assist CED in performing tasks, concerning the assurance of safety, effectiveness, and efficiency in use of medical equipment. Requirement analysis, resulted in the following features, that the system should include:

- Management of files for medical devices, manufactures and suppliers;
- Follow up of all purchasing procedures starting from the request from the departments up to acceptance tests of the devices;
- Implementation and management of the quality and safety protocols and procedures, including the necessary documentation and data, presented in an appropriate and comprehensible format.
- Scheduling of all the routine procedures, like acceptance testing, preventive maintenance, quality and safety inspections;
- Follow up of all the corrective maintenance activities;
- Management and monitoring of the training provided by the CED;
- Monitoring of the quality of the overall performance of the department, using quality and cost indicators;
- Facilitating access to and exchange of vigilance related information;
- Data analysis and report generation either predefined or customized by the users.

The above main requirements have been taken into consideration at the design phase of the system.

B. Design

The system structure is based on star model configuration. The central core unit caries out tasks, concerning the overall management of CED, and assures integration and communication of the whole system. On the other hand, each peripheral module addresses tasks related to more specific CED services. This leads to design approach of modular character. Each module has a specific scope and functionality. The main software package (the central core unit) is designed to cover all the functionalities needed to assist the CED in performing its main services. The peripheral modules either work as stand alone packages or are integrated in the system, when a specific service is performed. Flexible communication connection between the different software modules plays an important role for the level of integration of the whole system.

Report Documentation Page

Report Date	Report Type	Dates Covered (from... to)
25 Oct 2001	N/A	-

Title and Subtitle An Integrated Software System for Medical Equipment Management	**Contract Number**
	Grant Number
	Program Element Number
Author(s)	**Project Number**
	Task Number
	Work Unit Number
Performing Organization Name(s) and Address(es) Department of Medical Physics School of Medicine University of Patras, 26500, Rio-Patras, Greece	**Performing Organization Report Number**
Sponsoring/Monitoring Agency Name(s) and Address(es) US Army Research, Development & Standardization Group (UK) PSC 802 Box 15 FPO AE 09499-1500	**Sponsor/Monitor's Acronym(s)**
	Sponsor/Monitor's Report Number(s)

Distribution/Availability Statement
Approved for public release, distribution unlimited

Supplementary Notes
Papers from 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, October 25-28, 2001, held in Istanbul, Turkey. See also ADM001351 for entire conference on cd-rom.

Abstract

Subject Terms

Report Classification unclassified	**Classification of this page** unclassified
Classification of Abstract unclassified	**Limitation of Abstract** UU

Number of Pages
4

C. Implementation

Each unit has been developed in a software package, performing its functionality. All the software packages are installed and work on a PC, under Microsoft Windows operating system. The packages were developed using different programming languages, as the most suitable one was chosen, according to specific functionality of the software package.

The development of the user interface, with emphasis on usability and functionality characteristics, was of primary importance. Each package possesses its own database, as well as, tools for data processing, analysis and presentation.

Currently, the integrated system is comprised of three software packages: the overall management module, the information exchange module, and the quality control protocols module. Due to its open architecture, new specific modules can be easily included and integrated into the system, providing new functionalities and addressing new services.

D. Evaluation

The evaluation was an integral part of the system development. It has been accomplished in three levels including: testing, verification and validation. The scope was to ensure the system functionality. Testing procedures involved internal evaluators, as well as, professionals in software evaluation, having knowledge of the system structure. Testing goal was to determine the proper functionality of the system, monitoring of problems, related to database management, weak points in the software packages. Moreover the integrated system has been distributed for verification to a number of external end-users – the CED. Feedback comments have been collected, analyzed and consequently improvements were introduced. The installation of the system includes training and education of the CED staff, and technical support.

III. Results

The integrated system, shown schematically in Fig. 1, is comprised of the following software modules:

- PRAXIS – the main core module, prototype software tool for the comprehensive management of biomedical technology, both medical equipment and CED.
- Information exchange module for vigilance purposes – a telematics application, used as a common software platform for the exchange of vigilance related information for medical devices.
- Quality control protocols module – a software tool to support the quality assurance of medical equipment and quality control services.

A. PRAXIS

PRAXIS is a software tool for the overall management of medical equipment. The system aims to assist the CED in performing its tasks and improving the services carried out. PRAXIS consists of several sub-modules of different functionalities (Fig. 2.).

The *Inventory* sub-module comprises medical equipment recording and archiving procedures, facilitates management of information relevant to the device type (model and manufacturer) and device group. It also includes full information about device location and relocation, acquisition, technical support, cost and supplementary data.

The *Hospital* sub-module comprises information about the hospital itself, its departments, personnel and specialties. Detailed hospital profile is also available, presenting an additional general hospital information, including its identity data, such as address, number of beds, number of personnel, etc. and data relevant to the CED and its staff.

The *Data* sub-module comprises all the information stored in predefined catalogs supported by the system (suppliers, manufactures, third party organizations), as well as, data regarding the types of failures that have occurred, or can potentially occur to medical equipment.

The *Libraries* sub-module consists of a predefined list of measurements, available periodic inspection protocols, books, manuals or other documents existing in the CED's or in the hospital's library.

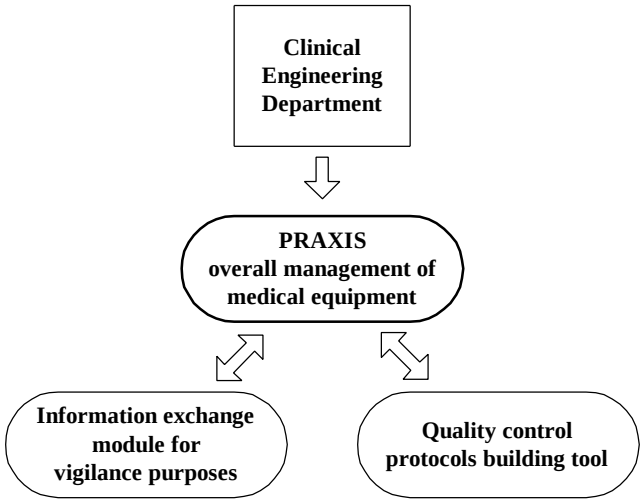

Fig. 1. Relationship between the modules of the integrated system.

The *Services* sub-module, concerns the system management supporting possibilities. It covers basic maintenance and management operations. It includes Acquisition, concerning new device purchase, offer estimation and contract management; Periodic inspections of medical devices; Training and Seminars, addressed to hospital personnel. The Vigilance section communicates with the Vigilance information exchange software package and receives data about adverse incidents, occurred elsewhere.

PRAXIS is developed following an open architecture, ensuring the maximum possible flexibility for the users, as well as, the maintainability of the software. It fully covers the services and the activities, performed by a modern CED.

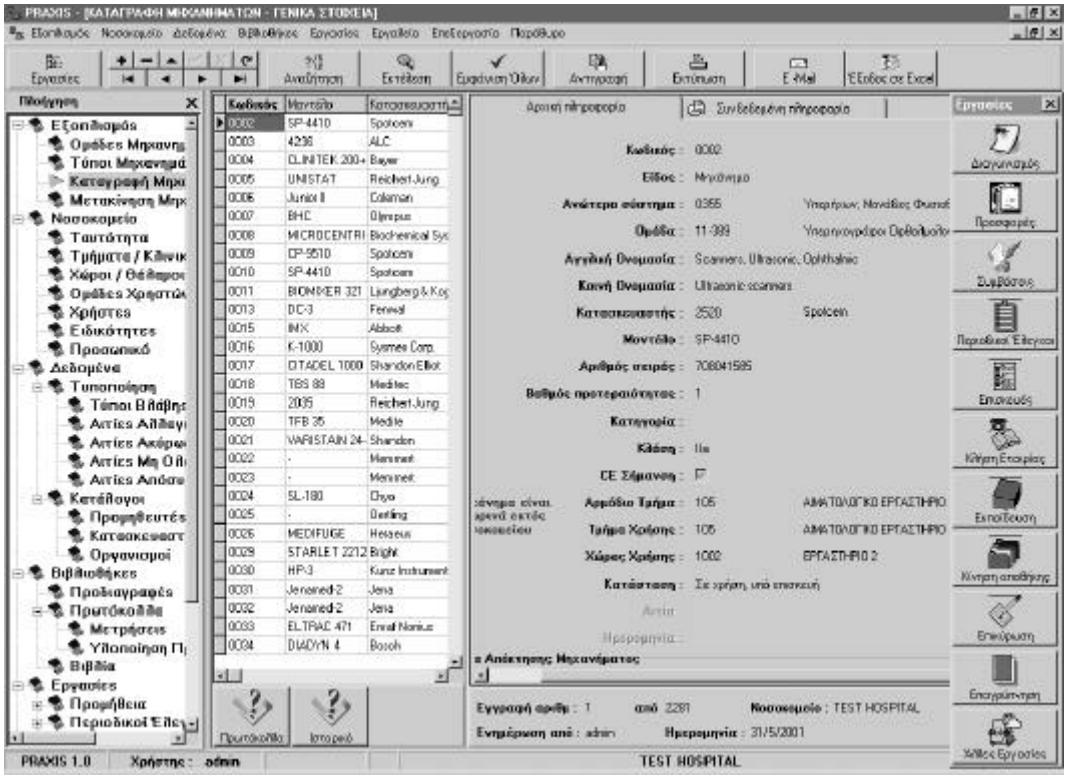

Fig. 2. PRAXIS inventory main screen.

B. Information exchange module for vigilance purposes

The Information exchange module (screen shots, shown in Fig. 3) for vigilance purposes is a telematics application to be used as a common software platform for the exchange of vigilance related information for medical devices between CEDs. It represents user reporting system by which the department informs for adverse incidents, and gets informed for relevant ones occurred elsewhere. It includes a *Database module*, allowing the creation, archival and management of the medical device vigilance related information and more specifically incident records, reports and requests, as well as, data pertinent to manufacturers, notified bodies and medical devices. The incident records are stored in the local database and they are used only for hospital's internal purposes. The communication is accomplished by a C*ommunication module*, supporting the exchange of data between hospitals, having the same system, in a secure, reliable and timely manner through the Internet. Security is assured by encryption of the interchanged messages.

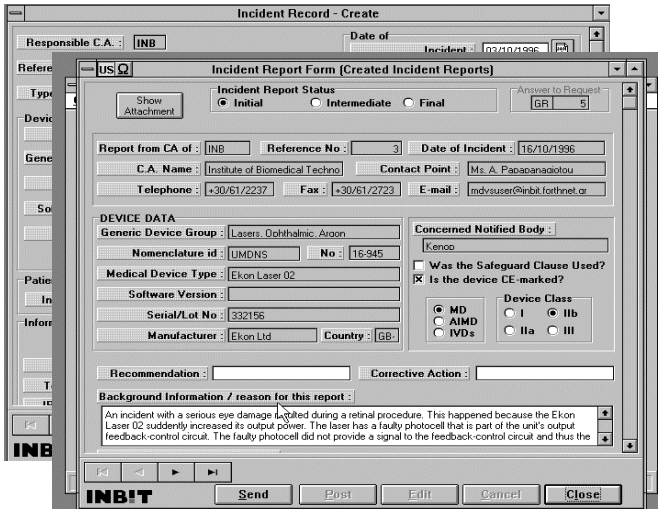

Fig. 3. Information exchange module screen-shots.

C. Quality Control Protocols module

Quality Control Protocols software package is an application for the overall management of quality control (QC) and inspection of medical devices. It provides the necessary flexibility to accommodate the different degrees of difficulty and specialization in creating or customizing QC protocols, carrying out inspections and managing collected data. Different categories of users perform different tasks in the QC procedure, which imposes a functional differentiation in three modules, each one assigned for a specific category.

The *Author* sub-module is used for the creation of new protocols and the customization of existing ones. The protocol development approach is facilitated by means of a number of functions for setting up the protocol structure, defining sub-processes and activities and assigning relative information to each one of them. Process documentation is performed in the form of a multimedia presentation.

Individual processes can be described by text, images, recorded audio passages or short video sequences. The protocols can be represented as trees, flowcharts or both. Tree diagrams (Fig. 4) are used to show relationships between sub-processes and their component elements and assignment of quality parameters to the measurement activities. Flowcharts are suitable for describing existing processes or designing new ones.

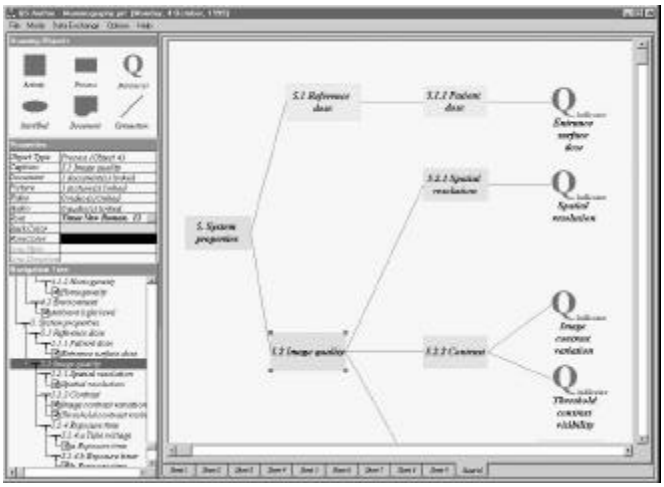

Fig. 4. Quality control protocol authoring sub-module.

The *Scheduler* sub-module provides the basic functionality for establishing the QC program in the clinical engineering departments. It provides the functionality for creating an inventory of equipment undergoing periodic inspection, quality control or preventive maintenance. Furthermore, the *Scheduler* is used to correlate protocols to equipment items and initiate a data file for the collection and storage of QC data. It creates schedules and produces daily job lists.

The *Sessions* sub-module is used to support the implementation of the sessions according to the established QC protocols, record data and analyze results. Its basic functionality includes data input, report generation, as well as, browse and view functions for multimedia documents. It presents information for the functional and technical condition of the biomedical equipment subjected to the tests. The processed measurement results and the outcome of the QC tests are included in a final report, used for decision-making concerning equipment condition, reliability and safety.

IV. Discussion

The proposed integrated system possesses advantages, concerning the system architecture, the separate software modules and the flexible data exchange communication. The separate modules and sub-modules architecture offers narrow services differentiation and detailed medical device management, complete documentation and explicit data analysis. The daily technology evolution provokes the development of new management tasks and their necessary and timely implementation in practice. Therefore the system provides possibilities for expansion by creating new peripheral modules.

The advantages of this integrated system are related to flexible management of small databases, avoiding problems with lost and corrupted records, higher system reliability, customized search engines, high record processing speed, system flexibility and real time data presentation and analysis. Furthermore, the implementation of a flexible communication connection between these specific parts carries out the data transmission to the central module, producing daily reports for medical device condition and the necessary maintenance procedures, needed to be accomplished. All these features are expected to improve the appropriate medical device management.

The creation of such an overall management application allows minimal relational database support, and provides global work picture in the department.

The evaluation has proven the usability and multifunctionality of the system that efficiently support the overall management of medical equipment.

V. Conclusions

The broad use of this integrated system could improve the effective management of medical equipment with significant benefits relating to cost-efficiency and safety. It is expected to assist CEDs in organizing their services and managing their resources in a better way by the monitoring, analysis and evaluation of the quality indicators. Moreover, it will facilitate information exchange between Clinical Engineering Departments and promote the adoption of commonly accepted quality indicators and procedures.

VI. References

[1] T. Cohen, “Computerized maintenance management system: How to match your department’s needs with commercially available products”, *J. Clin. Eng.*, vol. 20, No. 6, pp. 457-468, November/December 1995

[2] S. Panousis, P. Malataras, C. Patelodimou, Z. Kolitsi, and N. Pallikarakis, “Development of a new clinical engineering management tool & information system (CLEMANTIS)”, *J. Clin. Eng.*, vol. 22, No. 5, pp. 342-349, September-October 1997